# TRANSPARENCY IN

# UNITED STATES GOVERNMENT RULEMAKING

## Table of Contents



## Introduction

Under the Transatlantic Economic Partnership (TEP), the United States and the European Union have agreed to identify ways and means to improve regulatory cooperation, including providing access to each other's regulatory procedures and developing agreed general principles/guidelines on such procedures. An important first step in this process is gaining a mutual understanding of the transparency of existing regulatory procedures in each other's territories, particularly at the Federal level in the United States and the Community level in the EU.

The purpose of this paper is to describe the U.S. system of transparency in rulemaking used at the

Federal level to establish product regulations.[1] While this paper discusses the U.S.'s overall regulatory scheme, it focuses primarily on the informal rulemaking process set forth in the Administrative Procedure Act, 5 U.S.C. §§ 551, *et seq*. (APA). This focus is appropriate since rules specifying requirements for products are generally subject to the APA and are adopted by U.S. Federal agencies using, for the most part, the informal rulemaking process.[2] This paper is expected to provide the basis for a bilateral discussion of U.S. rulemaking. The European Commission has agreed to provide a comparable paper for discussion.

## Federal Rulemaking

### Congressional Authorization

While Congress could establish product regulations legislatively, instead it usually delegates authority to regulatory agencies to establish such regulations administratively pursuant to congressional guidance. The degree of specificity in the guidance varies from statute to statute. At one end, Congress may establish performance requirements. At the other, Congress may provide more general direction concerning factors to be considered and policy goals to be achieved. The latter is, by far, the more common practice.

When Congress enacts legislation creating a regulatory agency, or giving new authority to an existing regulatory agency, it typically includes provisions that implicitly or explicitly delegate its rulemaking authority to the agency with respect to a specified policy goal.[3] Rulemaking is agency action that regulates the future conduct of governmental agencies and persons,[4] through formulation and issuance of an agency statement designed to implement, interpret or prescribe law or policy. The legislation containing the authority granted by Congress to an agency is known as the agency's "enabling" legislation.

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[1] Given its relative brevity, this paper makes general statements about requirements applicable to the development, issuance and review of product regulations. It is important to note that the statutes relating to some types of product standards create exceptions to those generalizations. This paper does not attempt to identify or catalogue those exceptions, although it does note some of them.

[2] The distinction between the formal and informal rulemaking processes can be found in the section on the APA. That section begins on page 8.

[3] The general purposes include such goals as reducing pollutants harmful to public health or welfare, meeting the need for motor vehicle safety or ensuring food or drug safety.

[4] "Persons" are defined broadly in the APA as "an individual, partnership, corporation, association, or public or private organization other than [a U.S. Federal ] agency." "Persons" include persons located outside the United States.

While the enabling legislation specifies the general purposes for which rulemaking may be conducted, it normally does not identify the individual rules to be adopted to achieve those purposes. The legislation often enumerates the factors that an agency must consider in its rulemaking and may specify criteria that the resulting rules must meet. Those factors and criteria typically include practicability (often both economic and technological) and address the role that the cost of compliance is to play in the agency's rulemaking.

Occasionally, Congress supplements an agency's enabling legislation by enacting legislation directing the agency to use its general rulemaking authority in a specific way. In these instances, Congress directs the agency to issue at least a notice of proposed rulemaking, and sometimes a Final Rule as well on a particular subject. Congress has enacted such legislation when it has concluded that an agency should initiate or increase its efforts regarding a specific aspect of the problems that the agency is authorized to address through rulemaking. Even in these cases, Congress normally leaves the technical details of the rule to be issued to the discretion of the issuing agency. Congress almost never dictates what the specific performance requirements should be adopted for products, nor does it typically specify any details about regulatory approach, level of stringency or test procedures (although it may impose certain restrictions or define certain parameters).

In addition to enabling legislation, there are various other sources of requirements that govern the development and issuance by Federal agencies of rules regulating products. These sources include other statutes and Presidential Executive Orders that impose procedural requirements which are intended to ensure reasoned and fair decisionmaking. They require that the agencies adopt these rules only after thoroughly analyzing their potential impact, typically by means of an assessment and comparison of either the benefits and costs or the cost-effectiveness of alternative regulatory approaches or levels of stringency. They also require an open and transparent U.S. regulatory process that affords all participants equal treatment -- from the proposed rule through to the final rulemaking.

Regulations issued by agencies as Final Rules are subject to Congressional review under the Congressional Review Act, 5 U.S.C. §§ 801, *et seq*. (CRA) and to Congressional oversight. The CRA establishes a process through which Congress may reject any agency rule. A rule is rejected if both houses of Congress adopt a joint resolution by majority vote and if the President then approves the resolution. In the case of a "major rule," the CRA provides that such a rule may not take effect

sooner than the end of the 60-day period following the submission of the rule to Congress.[5] Under the CRA, Congress can neither amend a rule nor direct the a rule be amended. Congress can either take no action or disapprove a rule. The effect of a disapproving vote is to nullify the rule. Since enactment of the CRA in 1996, several joint resolutions of disapproval have been introduced in Congress. However, only one of those resolutions was voted on, and it was not adopted by the Senate. Apart from the CRA, Congress may also nullify an agency's rule by enacting new legislation that prohibits the agency from using appropriated funds to enforce the rule or from adopting. Alternatively, Congress may enact legislation identifying the regulatory provisions to which it objects and prohibiting the agency from issuing or maintaining a rule containing those provisions. All methods used by Congress to nullify a rule must, of course, be in accordance with the U.S. Constitution.

**Agency Action**

Most rulemaking proceedings by U.S. Federal agencies are initiated in one of the following three circumstances. First, the agencies may begin a rulemaking proceeding on their own initiative within the limits of their existing enabling legislation or other legislation granting them authority to engage in rulemaking. Second, Federal agencies may also initiate rulemaking within the limits of their existing authority in response to a request by the public. The APA provides that each agency of the U.S. government shall afford interested persons the right to petition for the issuance, amendment, or repeal of a rule. Some statutes provide explicit rights to petition. Where statutes do not so provide agencies may establish a petition process. Agencies must respond to such a petition. If the petition is meritorious and consistent with the agency's priorities and available resources, the agency will grant the petition and begin a rulemaking proceeding. The granting of such a petition and the commencement of a rulemaking proceeding do not necessarily mean that the requested rule will be issued. A decision as to the issuance of the rule is made on the basis of all available information developed in the course of

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[5] A "major" rule is defined for the purposes of the CRA as a rule that the Office of Management and Budget finds will result in any of the following:

(a) an annual effect on the economy of $100,000,000 or more;

(b) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

As a practical matter, a major rule would rarely be scheduled to go into effect shortly after its publication in the Federal Register. This is because the economic or public impact of the rule would make it necessary for the issuing agency to specify an effective date that is significantly later than the date of issuance. Thus, it is very unlikely that the CRA would cause a delay in the implementation of a major rule (unless, of course, Congress disapproved the rule).

the rulemaking proceeding, in accordance with statutory criteria. Third, an agency may be statutorily directed by Congress to begin a specific rulemaking proceeding.

*Public Access to Information*

The official U.S. Government document for publishing all regulatory documents is the Federal Register. The Federal Register, which is published each business day, includes all rules, proposed rules, and notices issued by Federal agencies and organizations, as well as Executive Orders and other Presidential Documents. The publication is available in hard copy on a paid subscription basis. It is also available online (http://www.access.gpo.gov/nara/#fr) without charge.[6] In addition, U.S. Federal agencies make extensive use of the Internet to provide information on their regulatory activities and enhance the transparency of their regulatory processes. However, it should be noted that the agencies' posting of such information on the Internet does not constitute an official publication.

The Office of Management and Budget (OMB) publishes the Unified Agenda of Federal Regulatory and Deregulatory Actions (Agenda) in the Federal Register each April and October. This publication contains a brief description of and schedule for each new rule that each agency is likely to issue in

[6] In the electronic version of this document, this and the other web addresses are hypertexted or "hotlinked," i.e., clicking a mouse on the address should automatically cause that website to appear on screen.

proposed or final form within the next twelve months.[7] It also lists each existing regulation that each agency is likely to review during that same period. By reading the Agenda, persons can learn whether any of the new rules being developed by the agencies are classified as significant under Executive Order 12866, Regulatory Planning and Review, and thus subject to review by OMB. (See the sections below on Inter-agency and Inter-governmental Participation and on Other Rulemaking Requirements for fuller discussions of the Executive Order. The definition of "significant regulatory actions" appears in a

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[7] There are limitations to the information in the Unified Agenda. As the Regulatory Information Service Center (RISC) of the General Services Administration noted in its introduction to the most recent agenda:

> Agencies prepared entries for this publication to give the public notice of their plans to review, propose, and issue regulations. They have tried to predict their activities over the next 12 months as accurately as possible, but dates and schedules are subject to change. Agencies may withdraw some of the regulations now under development, and they may issue or propose other regulations not included in their agendas. Agency actions in the rulemaking process may occur before or after the dates they have listed.
>
> The Unified Agenda does not create a legal obligation on agencies to adhere to schedules within it or to confine their regulatory activities to those regulations that appear in this publication. The information in this edition is accurate as of April 1, 1999, in the judgment of the submitting agencies, except as otherwise noted by the agencies. In addition, some agencies submitted updates after that date.

(April 26, 1999; 64 F.R. 20940, at 20941)

The rulemaking activities of each agency appear in the Unified Agenda under one of five headings according to the rulemaking stage of the activity. According to RISC, the stages are:

> 1. Prerule Stage -actions agencies will undertake to determine whether or how to initiate rulemaking. Such actions occur prior to a Notice of Proposed Rulemaking (NPRM) and may include Advance Notices of Proposed Rulemaking (ANPRMs) and reviews of existing regulations.
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> 2. Proposed Rule Stage -actions for which agencies plan to publish a Notice of Proposed Rulemaking as the next step in their rulemaking process or for which the closing date of the NPRM Comment Period is the next step.
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> 3. Final Rule Stage -actions for which agencies plan to publish a final rule or an interim final rule or to take other final action as the next step in their rulemaking process.
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> 4. Long-Term Actions -items under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda.
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> 5. Completed Actions -actions or reviews the agency has completed or withdrawn since publishing its last agenda. This section also includes items the agency began and completed between issues of the Agenda.

(Id., at 20942)

footnote to the former section.) Persons wishing to find out more about a particular rulemaking may contact the individual listed in the Agenda for that rulemaking.

The most recent Unified Agenda was published April 26, 1999. That Agenda includes descriptions of slightly more than 4,500 rules, listed by agency, at various stages in the regulatory process. Not all of these projects concern product requirements. The Agenda can be viewed on-line by going to http://reginfo.gov/.

After the publication of a Final Rule in the Federal Register, the rule is codified, along with all existing regulations, in the Code of Federal Regulations (CFR). The CFR is divided into 50 titles which represent broad areas subject to Federal regulation. Each title is further divided into chapters, which usually bear the name of the issuing agency. Each chapter is subdivided into parts covering specific regulatory areas. The index refers users to the appropriate titles and chapters affecting specific areas. The CFR is updated annually. It is published in paperback form for a charge and is available free of charge on the Internet at www.access.gpo.gov/nara/#cfr.
The documents that an agency relies upon or considers in issuing a Final Rule are placed by the agency in a public docket where they are available for public inspection and comment. Each docket is identified by a docket number. These documents include studies generated by the agency to support its position as well as comments submitted in response to the agencies documents (except documents that have been submitted confidentially).[8] While some agencies accept and rely upon confidential information in their rulemakings, others do not.

Federal agencies make extensive use of the Internet to provide information related to their regulatory activities and enhance the transparency of their regulatory process. Many agencies either have established or in the process of establishing an electronic docket system. For example, the Department of Transportation and the Food and Drug Administration have established systems that permit a person anywhere in the world to view and download documents that have been submitted to any of their rulemaking dockets. (http://dms.dot.gov/) (http://www.fda.gov/ohrms/dockets/default.htm). The Department of Transportation system also permits people to file comments electronically. Other agencies have conducted public meetings via the Internet, eliminating the need for persons to travel to a particular geographical location in order to participate. Some agencies, like the Environmental Protection Agency, provide links to electronic versions of all of the rulemaking documents that they have recently published in the Federal Register. (See

[8] "Trade secrets and confidential business information" mean records or data submitted to the government that arguably contains material exempt from release under exemption 4 of the Freedom of Information Act, 5 U.S.C. § 552(b)(4), because disclosure could reasonably be expected to cause substantial competitive harm to the entity submitting the information. Persons submitting documents confidentially must assert their claim to confidential treatment at the time the documents are submitted. The agency then makes a determination as to whether exemption 4 applies. This exemption applies during all stages of the rulemaking process. As noted above, not all agencies accept documents containing trade secrets or confidential business information in their rulemakings.

http://www.epa.gov/epahome/rules.html#proposed). In addition, agencies are posting a wide variety of information relating to their rulemakings, such as research reports and analyses so that they can be examined online and downloaded without charge. Links to all Federal departments in the President's Cabinet and to all independent agencies and commissions can be found at: http://reginfo.gov/.

Federal agencies are required by the Freedom of Information Act (FOIA) (5 U.S.C. § 552) to make records in their possession available upon receipt of a request that reasonably describes the records desired by the requestor. The purpose of this Act is to expand the areas of public access to information beyond those originally set forth in the APA. The Act gives any person the right to request records from agencies. Upon receipt of a request, an agency must search for records responsive to the request. The agency must then make available copies of all responsive records located in the search, unless the records are protected from disclosure under one of nine statutory exemptions in the FOIA.[9] Public access to government information was broadened in 1996 by the enactment of the Electronic Freedom of Information Act Amendments (E-FOIA). The E-FOIA requires agencies to make more material available electronically. In addition, the FOIA was supplemented by Executive Order 12600, Predisclosure Notification Procedures for Confidential Commercial Information (1987), which gives private parties, especially business firms (including foreign firms), a right to prior notice before an agency releases information about or received from the firm.

*Public Participation*

Private citizens, industry, and organizations can participate in an agency's rulemaking activities in variety of ways. In addition to the opportunity to submit comments and petitions as discussed below in the section of the APA, persons can contact directly contact the agencies in accordance with the agencies' own particular procedural requirements, participate in advisory committees formed by the agencies, or participate in negotiated rulemakings.

While the APA limits ex parte oral communications in formal rulemakings, it does not do so in informal rulemakings.[10] However, the various Federal agencies have adopted their own policies about such communications during informal rulemakings. These policies vary . Some agencies discourage, but do not prohibit, ex parte oral communication during all stages of a rulemaking proceeding, even before an NPRM is issued. Other agencies discourage ex parte oral communications only after an NPRM has been issued. Still others permit them at any time during a rulemaking proceeding. In all cases,

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[9] In addition to the exemption noted above for trade secrets and confidential business information, exemptions are also provided for other matters such as inter-agency or intra-agency memorandums or letters, and records or information compiled for law enforcement purposes. (5 U.S.C. § 552(b)(5) and (7)).

[10] "Ex parte communication" is defined in the APA as meaning "an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding..." (5 U.S.C. § 551(14)).

however, to the extent that an agency wishes to rely in its Final Rule on information or data received in ex parte oral communications, it must document the substance of the communications in a memorandum that is made publicly available. Such documentation is necessary to ensure that the public and the courts (in the event of a lawsuit) are aware of the communications.

Federal agencies may meet with committees or groups of persons to augment the opportunity for dialogue and public input in their rulemakings. Some of these committees or groups may be advisory committees within the meaning of the Federal Advisory Committee Act, 5 U.S.C. App. 2 (FACA). Under the Act, an advisory committee is any committee or group containing at least one member who is not a full-time Federal employee, that is established or utilized by a Federal agency, in the interest of obtaining consensus advice or recommendations. Advisory committees may be established under the FACA after public notice is given and a determination is made that the formation is in the public interest. The committees must have a charter and a clearly defined purpose, and membership must be fairly balanced in terms of the points of view represented and functions performed. Generally, meetings of the advisory committees are announced in the Federal Register and are open to the public. Minutes of the meetings and all related documents are public.

The Negotiated Rulemaking Act of 1990 (NRA) establishes a framework for conducting a negotiated rulemaking and encourages agencies to use negotiated rulemaking to enhance the informal rulemaking process. 5 U.S.C. §§ 561, *et seq*. The premise underlying negotiated rulemaking is that bringing together representatives of an agency and of the various affected interest groups to negotiate, and reach consensus on, a proposed rule will lessen the likelihood of litigation when a Final Rule is issued. Under the NRA, an agency forms an advisory committee consisting of representatives of the affected interests and representatives of the agency for the purpose of reaching consensus on a rule to be issued in a notice of proposed rulemaking. The committee is subject to the FACA, and thus generally must hold its meetings in public. The negotiations within the committee are assisted by a neutral facilitator. The goal of the committee is to reach consensus within the limits of the agency's legal authority and policy objectives for the rulemaking. If consensus is reached, the agency uses the product of the consensus as the basis of its notice of proposed rulemaking.

*Inter-agency and Inter-governmental Participation*

Federal agencies have various means for monitoring and coordinating with each other's regulatory activities. Agencies often directly consult on their own individual initiative with each other, formally and informally, on rulemaking issues of mutual interest, regardless of whether they are significant under Executive Order 12866. Typically, the consultation occurs initially on a working level among technical staff and later, as the agency's development of approaches to addressing the issues progresses, on a policy level as well. There are also inter-agency working groups, such as the Interagency Council on Standards Policy, that meet on an ongoing basis to discuss issues of mutual interest and to share information on their agency's activities.

Executive Order 12866 provides that each regulatory agency should avoid issuing rules that are inconsistent, incompatible, or duplicative with those of other Federal agencies. The Office of Management and Budget (OMB) is charged, under the Order, with coordinating inter-agency review of significant proposed or final rules prior to their issuance and publication in the Federal Register.[11] If the proposed or final rule of one agency would create a serious inconsistency or otherwise interfere with an action taken or planned by another agency, that rule is treated as a significant rule under the Order, and thus is subject to OMB review. OMB provides a copy of the affected rule to other interested agencies for comment during the review process.

*The Administrative Procedure Act*

The primary mechanism for ensuring transparent and open rulemaking in the U.S. is a standardized system of consultations with the public as rules are developed and revised. The APA specifies requirements for rulemaking, i.e., the process by which Federal agencies formulate, propose, establish, amend, or repeal a regulation. Substantive rules issued by an agency under the APA have the force and effect of law. If an agency's enabling legislation authorizes it to conduct rulemaking, the legislation typically specifies that either formal or informal procedures are to be followed:

- *Informal rulemaking* procedures require, with certain limited exceptions, that the agency provide prior notice and an opportunity to comment by submitting written data or arguments in response to the publication of a proposed rule. There are no restrictions on who may participate. Any person, regardless of geographical location, may submit comments. This includes, for example, government agencies of other countries. These procedures require also that the data and arguments be considered by the agency and that in issuing any Final Rules, the agency include a statement of the rule's basis and purpose and address the comments. A fuller

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[11] Section 3(f) of the Executive Order defines "significant regulatory action" as

> any regulatory action that is likely to result in a rule that may:
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> > (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
> >
> > (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
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> > (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
> >
> > (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

discussion of informal rulemaking procedures is provided later in this paper.

- *Formal rulemaking* procedures require an agency to conduct a complete oral, evidentiary hearing. These hearings are open to all persons. The agency must offer persons who wish to participate an opportunity to appear and present oral and documentary evidence and views and to cross-examine other participants in the hearing. The hearings are generally presided over by an Administrative Law Judge. The record consists of the transcripts of the testimony and exhibits presented at the hearing, together with all documents filed in the proceeding.

Informal rulemaking procedures are required for most rulemakings, including most rulemaking involving the establishment of product requirements. Formal rulemaking has been, and continues to be, the exception. An agency must use formal rulemaking procedures if it is rulemaking under a statute requiring that rulemaking be conducted "on the record." Most of the relatively few agencies required to use these procedures are independent regulatory commissions, such as the Federal Communications Commission. These commissions use formal procedures for such actions as granting licenses and promulgating regulations or rates that are not generally applicable to all regulated persons.

Some statutes require the use of "hybrid" rulemaking procedures, in which informal written comments are supplemented with oral presentations of some kind. In addition, agencies subject to informal rulemaking procedures may, at their discretion, decide to use "hybrid" procedures. For example, they may decide to hold public meetings when they believe that it would be beneficial to have a face-to-face exchange of views and information between the agency and the public. As with formal rulemaking, hybrid rulemaking represents a very small portion of rulemaking government-wide.

Agencies can add to, but never subtract from, procedures required by the APA or other statutes. As mentioned earlier, agencies engaged in informal rulemaking sometimes voluntarily decide to hold public meetings. The additional procedures used by an agency must not violate the procedural requirements in the APA or other statutes, such as the rules concerning consideration of written comments during a rulemaking.

Informal rulemaking proceedings proceed in the manner set forth below. Not all steps, e.g., preliminary notices, must be used in all rulemakings. The vast majority of rulemakings involve only three steps: issuance of an notice of proposed rulemaking soliciting public comment, agency consideration of all relevant information including public comments, and the issuance of a Final Rule after consideration of the relevant information. Since a greater range of steps is particularly likely to be used in some of the more significant rulemakings, the full potential range of steps is outlined below. It should be noted that the duration of rulemaking can vary from a few months to several years depending on the complexity, controversality and nature of the action.

Preliminary Notices

Although the APA does not require or even address preliminary notices, they are issued by some regulatory agencies with sufficient frequency to warrant their discussion here. An agency contemplating rulemaking may decide that it wants to obtain additional information before developing and publishing a specific proposal for addressing a problem. In such cases, to obtain more information about the nature and extent of a possible problem or to obtain public views on which regulatory approach would be most effective and desirable, the agency may publish a preliminary notice seeking public comments.

The most common type of preliminary notice is the Advance Notice of Proposed Rulemaking (ANPRM). It is a means of public outreach and opportunity for public comment early in the rulemaking process. It describes the general area that may be the subject of a proposed rule and usually asks for public comment on the issues and regulatory options being considered. It invites the public to identify any additional relevant issues.

The ANPRM specifies a certain period of time within which the public may submit comments. Comments may be submitted by anyone. The agency places all comments in a docket where they are available to the public, except that trade secrets and confidential business information are not revealed. The comment period is usually 30 or 60 days, but it can be longer or shorter, depending on the circumstances.

Notice of Proposed Rulemaking

In most cases, the initial step in the rulemaking process is to develop and then publish a proposed rule. The proposal is called a Notice of Proposed Rulemaking (NPRM). The purpose of the NPRM is to inform the public about the proposal and request public comment on it. The NPRM typically consists of two parts: a preamble, which is a narrative discussion, and proposed regulatory text. The amount of detail in preambles varies. The more detailed preambles identify the problem addressed by the proposal, discuss and analyze information regarding the existence, nature and extent of the problem, explain how the proposal will ameliorate that problem, and analyze the benefits and costs of the proposal. If the NPRM was preceded by the issuance of a preliminary notice, the NPRM summarizes and responds to the public comments on the preliminary notice. The NPRM identifies an agency contact who can reply to questions and an address to which comments may be sent. To the extent that the NPRM does not set forth and explain the factual assumptions, analyses and methodologies underlying the proposal, the agency places documents containing those matters in a public docket so that the public has an opportunity to comment on them.

The NPRM specifies a certain period of time within which any person who wishes to do so may submit comments. The agency places all comments in a public docket, except that trade

secrets and confidential business information are not revealed. The comment period is usually 30 or 60 days, but can be longer or short, depending on circumstances. The North American Free Trade Agreement specifies a 75-day comment period for NPRMs with a significant impact on trade. This public comment process serves a number of purposes, including giving persons the opportunity to:

-- provide the agency with information that will enhance the agency's knowledge about matters related to the proposal; and

-- challenge the factual assumptions, analyses, and tentative conclusions underlying the agency's proposal and show in what respect they are in error.

If, after the comment period, the agency obtains new information or analysis that is not simply cumulative and has a potentially significant bearing on the substance of the Final Rule, the agency must make it available so that the public may provide comments. If the agency has an established practice of considering late comments and is prepared to consider any late comments on the new information or analysis, it need not re-open the comment period on the NPRM. If the new information or analysis has particularly great significance, the agency should take steps to ensure public awareness that the material has become available.

In response to the comments on the NPRM or developments (e.g., new research results) after the NPRM is issued, the agency generally changes certain aspects of the proposal. In most cases, the changes are within the range of regulatory approaches discussed in the NPRM, and no further opportunity for public comment is required. However, if any of the changes desired by the agency involve matters neither discussed in the NPRM nor a logical outgrowth of those matters, the agency must give the public a chance to comment on a revised proposal before issuing a Final Rule. To provide that chance, the agency issues a Supplemental Notice of Proposed Rulemaking.

Supplemental Notice of Proposed Rulemaking

The SNPRM identifies changes to the proposed rule that were not reasonably anticipated in the NPRM. It also may identify significant new factual information that was not included in the record of the rulemaking at the NPRM stage, and upon which the agency wishes to rely in the Final Rule. Like the NPRM, the SNPRM seeks public comment on the changed regulatory language and explains the basis for the new language. SNPRMs are issued significantly less frequently than ANPRMs.

Final Rule

After considering the comments, the agency decides whether to issue a Final Rule. Like

NPRMs, Final Rules include a preamble and regulatory text. If the agency issues a Final Rule, the preamble includes a detailed statement of the basis and purpose of the rule, explains why the agency agrees or disagrees with the substantive comments it received and describes the changes, if any, it made to the rule in response to the comments with which it agrees. Public comment is not solicited in a Final Rule. However, if the agency allows petitions for reconsideration, it must state that petitions for reconsideration may be submitted and may specify a deadline for doing so. The Final Rule also specifies a date on which the rule will become effective. A lead time of 1 to 3 years is not unusual, particularly in the case of significant rules or rules governing new technologies or products. If the agency decides not to issue a Final Rule, it issues a Notice of Withdrawal of the proposal, explaining the reasons for that action.

Normally, the APA requires that a Final Rule be published at least 30 days before it takes effect. However, compliance with the 30-day requirement is not necessary if the rule makes an exemption or relaxes existing requirements, or if the agency makes and publishes a finding that an earlier effective date is required "for good cause." This finding is made rarely.

Petitions for Reconsideration

Even after a Final Rule is issued, the public may have a final chance to request the agency to make changes to the rule. Members of the public can do this by submitting Petitions for Reconsideration. The submission of a Petition for Reconsideration generally does not delay the effective date of the rule.

Some agencies respond to Petitions for Reconsideration by making changes to the Final Rule without first soliciting public comment, if those changes are either within the scope of the NPRM or are a reasonable outgrowth of the NPRM. Other agencies may issue a new NPRM before making any changes in response to Petitions for Reconsideration, regardless of whether the changes are within scope.

In certain limited circumstances, an agency may publish a Final Rule without first issuing an NPRM and receiving and considering public comment. The APA provides an exemption from the notice and comment requirements for all rules relating to "public property, loans, grants, benefits, or contracts." However, these rules are still subject to the publication requirements of the APA. Moreover, many agencies have voluntarily waived this exemption and issued such rules after notice and comment. Congress has also passed some program-specific laws that establish public participation requirements for otherwise exempt rules.

In addition, the requirement for prior notice and an opportunity for public comment on other types of rules may be waived in cases in which the agency finds "good cause" that such procedures would be "impracticable, unnecessary, or contrary to the public interest." (5 U.S.C. § 553(b)(3)(B)). Pursuant

to this language, courts have occasionally allowed agencies to waive the notice and comment procedures and issue rules when the agency can show it is confronting one or more of the following "emergency" situations: (1) where an agency was subject to a short, statutorily-imposed deadline; (2) where an immediate rule is required to address a serious risk to public health and safety; (3) where advance notice would thwart the purpose of the rule; or (4) where immediate clarification of existing rules and regulations is needed to alleviate confusion. It is important to note that the "good cause" exception is to be construed narrowly. Further, agencies may not automatically waive informal rulemaking procedures whenever one of the aforementioned situations arises or in the agency's judgement an emergency situation exists. Instead, an agency must clearly demonstrate that the waiver of APA's notice and comment procedures is proper in a particular circumstance.

*Other Rulemaking Requirements*

In addition to the requirements in their enabling legislation, regulatory agencies are subject to other statutory requirements for analyzing various impacts of their proposed and final rules. Among these are requirements to analyze the impact of the rule on small business (the Regulatory Flexibility Act); the impact of the rule on the environment (the National Environmental Policy Act); and the impact of any information collection requirements contained in the rule (the Paperwork Reduction Act). These analyses, like the other required analyses, must be made public.

In addition, other requirements are established by the Executive Branch, including those contained in Executive Order 12866. The Order, which was issued on September 30, 1993, sets out an overarching regulatory philosophy and principles to guide agencies in developing effective and efficient rules. It requires that agencies assess both costs and benefits (quantitative and qualitative) of an intended rule and propose or adopt a rule only upon making a reasoned determination that the benefits of the intended rule justify its costs. The Order states that, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize benefits. One of the principal objectives of the Order is to make regulatory processes more accessible and open to the public. The Order encourages the use of consensual mechanisms for developing rules, including negotiated rulemaking. The Order requires that before regulatory agencies issue proposed and final "significant" rules, they submit them to OMB for review. Significant rules must be accompanied by an extensive regulatory impact analysis. The analysis is placed in the public docket to facilitate public comment on it. The Order can be found at http://reginfo.gov/eo12866.htm.

The National Technology Transfer and Advancement Act (NTTAA) of 1995 directs Federal agencies to use voluntary consensus standards, both domestic and international, in lieu of government-developed regulations, as a means to carry out policy objectives or activities determined by the agencies, except when doing so would be inconsistent with law or otherwise impractical. (Public Law 104-113) (15 U.S.C. § 272 note). See also OMB's Circular A-119. The Act further directs the agencies to participate in voluntary consensus standards development activities "when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and

budget resources ." Such participation is aimed at contributing to the development of voluntary standards that will minimize the need to develop and maintain separate government regulations. This legislation was enacted in recognition that many voluntary consensus standards are appropriate or adaptable for the Government's procurement and regulatory purposes. Circular A-119 also requires that regulatory agencies review their existing regulations at least every five years and rescind those for which adequate and appropriate voluntary standards can be adopted as a substitute.

Federal agencies are also required, in developing their regulations, to take into consideration relevant international standards and, if appropriate, base their regulations on those international standards. Title IV of the Trade Agreements Act of 1979 (Public Law 96-39), as amended 1994 (Public Law 103-465) and 1996 (Public Law 104-295) (19 U.S.C. § 2532(2)). The Act expressly provides that the reasons for which it may not be appropriate to base a regulation on an international standard include, but are not limited to, the protection of human health or safety, animal or plant life or health, or the environment.

**Agency Interpretive Statements**

Federal agencies often issue interpretations of their regulations and of the statutes that they administer, either in response to requests from regulated entities and other members of the public or on their own initiative. These interpretations do not have the same force of law as the law or regulation to which they apply. However, agencies and regulated parties may nevertheless treat them as binding as a practical matter (as opposed to a legal one). Interpretations are generally not subject to the APA notice and comment requirements that apply to rulemakings, unless notice or a hearing is required by an agency's enabling legislation, because interpretations do not establish or amend laws or regulations. Instead, they merely clarify laws and regulations that already exist.

Interpretative statements are not legally required to be published in the Federal Register. However, if an interpretative statement is not so published, persons without actual and timely notice of the statement may not be required to conform with the statement. The FOIA requires that each agency shall make available for public inspection and copying all statements of interpretation that have been adopted by the agency and have not been published in the Federal Register. 5 U.S.C. § 552(a)(2). Many agencies now do this by putting their interpretations in searchable databases on the Internet.

However, transparency is not required when formulating interpretations. Unlike rulemakings, interpretations do not involve the making of statutory judgements such as whether a requirement meets the need for vehicle safety or is practicable. An interpretation is based largely on reading the language of the regulation being interpreted, in light of the purpose of the regulation and the agency's general policy goals. These considerations are all well known to the agency. The only additional information the agency might need are facts surrounding the requester's particular situation, such as details of a particular vehicle's configuration or how it is typically used. When some vital fact is missing, the agency generally asks for clarification from the requester, who is in the best position to supply the information.

**Judicial Review**

All Final Rules establishing, amending or revoking regulations may be judicially reviewed pursuant to either an agency's enabling legislation, the APA or particular agency-specific statutes. In addition, other final actions are judicially reviewable, including denials of petitions for rulemaking, denials of petitions for reconsideration, and decisions to terminate rulemaking after the issuance of an NPRM. Although the percentage of rules issued through informal rulemaking and then judicially reviewed may be relatively small, there is a steady and significant number of cases involving procedural and/or substantive challenges. Further, given the precedential effect of court decisions, judicial review can have a significant and long-lasting effect on agency rulemaking.

The APA provides that a person adversely affected or aggrieved by a Final Rule may seek to have it overturned on a variety of grounds, e.g., for being arbitrary, capricious or an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706. Courts have regarded a person as being adversely affected when the person can demonstrate the likelihood of suffering harm and that the alleged harm is directly related to the challenged rule. A general allegation of harm, such as increased cost of the final product or higher taxes, is insufficient. Additionally, the person must show that judicial action could lead to redress of the alleged injury. Generally speaking, any person directly subject to a rule specifying product requirements relating to safety or health or any consumer interest group whose members purchase or use the products subject to such a rule may qualify as an adversely affected or aggrieved person.

Suits challenging agency rules typically allege both procedural and substantive grounds for overturning those rules. Among the procedural grounds are lack of adequate notice. Persons alleging lack of adequate notice often argue that the difference between the proposed and final regulatory text was so great that commenters could not reasonably have anticipated, and thus could not comment on, some important part of the Final Rule. Another common argument is that, in order to support the Final Rule, the agency relied on data or analysis that was not made known to commenters in time for them to offer comments before the Final Rule.

Moreover, many regulatory enabling statutes may specify procedures for rulemaking that extend beyond the general requirements contained in the APA. Likewise, an agency may issue procedural regulations that govern its rulemaking. In both instances, a failure by the agency to adhere to these additional procedures can result in the agency's rule being invalidated on judicial review.

To avoid having a rule overturned or remanded as arbitrary or capricious, an agency should: state the factual predicates for its rule; support the factual predicates by linking them to evidence in the rulemaking record; explain how it reasoned from factual predicates to the expected effects of the rule; relate factual predicates and expected effects to each of the relevant statutory goals, purposes or criteria that is made relevant by its statute; avoid basing any aspect of its Final Rule on factors which Congress did not intend to be considered; explain its reasons for agreeing or disagreeing with major

comments and for resolving issues raised by commenters as it did; and give reasons for rejecting plausible alternatives to the rule it adopted, especially those that arguably would better promote the goals of the statute under which the rule was issued.

A reviewing court generally will not substitute its judgment for that of the agency or overturn factual conclusions as long as the agency's conclusions have a substantial basis in the administrative record. (See discussion of administrative records below.) This is particularly true when the subject matter is technical, concerns a newly developing technology, or involves exercise of the agency's expertise.

A Final Rule revoking a regulation is subject to the same degree of judicial scrutiny as a Final Rule establishing or amending a regulation. There is a presumption that a settled course of agency behavior represents that agency's informed judgment that, by pursuing that course, it will carry out the policies committed to it by Congress. Thus, if the agency departed from past agency practices or positions in adopting a new rule, the agency must explain in some detail why it did so. For example, if the rule revokes a regulation, the agency must provide a reasoned analysis for the change beyond that which may be required when an agency decides not to adopt a rulemaking in the first instance.

The court's decision is based on the administrative record. The court will not consider any post hoc rationalizations by counsel in defending agency action. The administrative record is compiled by the agency and consists of the Final Rule, and all the information the agency had before it at the time of its issuance of the Final Rule, including the NPRM, all comments on the NPRM, and research results and reports. Non-public documents discussing internal agency deliberations are not part of the administrative record.

If the court overturns a Final Rule, it will return the rule to the agency for further consideration. The court may either vacate the rule, in which case, it has no legal effect; or the court may simply remand the rule, requiring the agency to reconsider its position, but leaving all or part of the rule in effect during that period of reconsideration. Simple remands often occur when undue harm could be caused in the absence of an applicable rule or when the remand is based on procedural deficiencies that are unlikely to change the agency's final decision. Only in rare circumstances, in which the agency has very limited discretion under its enabling legislation, will a court direct the agency to make a particular decision.

## Subfederal Rulemaking

The due process requirements of the U.S. Constitution ensure that State regulatory activity is open and transparent. To meet the Constitutional requirements of due process, most States have enacted statutes containing transparency procedures. For example, most States have enacted administrative procedure acts whose procedures are similar to those of the Federal Administrative Procedure Act. The majority of States have also enacted statutes that provide for public access to information and judicial procedures.

Federal laws and regulations may either expressly or impliedly preempt State law. Statutory preemption exists when Congress adopts language specifically providing that States cannot adopt or maintain any regulation that differs from the Federal regulations. Federal law may also impliedly preempt State law if (1) Congress has fully occupied the particular field of regulation in question; or (2) the State law conflicts with any Federal law or interferes with the objectives of Federal law.

## World Trade Organization

Title IV of the Trade Agreements Act of 1979 provides the legal basis on which the Tokyo Round Agreement on Technical Barriers to Trade (TBT) was implemented in the United States. See 19 U.S.C. §§ 2531 *et seq*. Conforming amendments to that legislation were made by the Uruguay Round Agreements Act (Public Law 103-465). The Administration's Statement of Administrative Action, which accompanied this law, sets forth the detailed plan to guide the Executive Branch in implementing the obligations under the WTO TBT (and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)).

The U.S. enquiry point, the National Institute of Standards and Technology (NIST), provides interested parties with specific regulatory information/contacts in response to requests received. The Office of the U.S. Trade Representative (USTR) monitors implementation of transparency provisions relating to U.S. obligations under the WTO and other trade agreements.

## Glossary of Acronyms

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| ANPRM | Advance Notice of Proposed Rulemaking |
| APA | Administrative Procedures Act |
| CFR | Code of Federal Regulations |
| CRA | Congressional Review Act |
| FACA | Federal Advisory Committee Act |
| FOIA | Freedom of Information Act |
| FR | Federal Register |
| NIST | National Institute of Standards and Technology |
| NPRM | Notice of Proposed Rulemaking |
| NRA | Negotiated Rulemaking Act |
| NTTAA | National Technology Transfer and Advancement Act |
| OMB | Office of Management and Budget |
| RISC | Regulatory Information Service Center |
| SNPRM | Supplemental Notice of Proposed Rulemaking |
| USC | United States Code |
| USTR | United States Trade Representative |

## Further Reading

Kenneth Culp Davis and Richard J. Pierce, Jr., Administrative Law Treatise. Published by Little, Brown and Company (3rd ed. 1994). This 3-volume set is one of the sources for this document.

Jeffrey S. Lubbers, A Guide to Federal Agency Rulemaking. Published by the American Bar Association's Government & Public Sector Lawyers Division and the Section of Administrative Law & Regulatory Practice (3rd ed.1998). The Guide is organized into six parts, including parts on:

- The statutory structure of rulemaking, including relevant sections of the Administrative Procedure Act (APA) and other statutes that impact current rulemaking
- A step-by-step description of the informal rulemaking process, from preliminary considerations to the Final Rule
- A review of the law on judicial review of agency rulemaking, examining cases decided in recent years
- An Appendix including key federal statutes and other rulemaking documents